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(51) International Patent Classification ⁷ : A61K 38/21, 31/7056, A61P 31/14	A3	(11) International Publication Number: WO 00/37110 (43) International Publication Date: 29 June 2000 (29.06.00)
(21) International Application Number: PCT/US99/27935 (22) International Filing Date: 16 December 1999 (16.12.99) (30) Priority Data: 09/215,876 18 December 1998 (18.12.98) US (71) Applicant: SCHERING CORPORATION [US/US]; 2000 Galloping Hill Road, Kenilworth, NJ 07033 (US). (72) Inventors: GLUE, Paul, W.; 13 Allens Comer Road, Flemington, NJ 08822 (US). ALBRECHT, Janice, K.; 1308 Temple Grove Court, Winter Park, FL 32789 (US). (74) Agents: HOFFMAN, Thomas, D. et al.; Schering-Plough Corporation, Patent Dept. K-6-1 1990, 2000 Galloping Hill Road, Kenilworth, NJ 07033-0530 (US).		(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, HR, HU, ID, IL, IN, IS, JP, KG, KR, KZ, LC, LK, LR, LT, LU, LV, MA, MD, MG, MK, MN, MX, NO, NZ, PL, PT, RO, RU, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UZ, VN, YU, ZA, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> (88) Date of publication of the international search report: 14 September 2000 (14.09.00)
(54) Title: RIBAVIRIN-PEGYLATED INTERFERON ALFA INDUCTION HCV COMBINATION THERAPY (57) Abstract The use of ribavirin and interferon alpha for the manufacture of pharmaceutical compositions for treating a patient having chronic hepatitis C infection, e.g., a patient having HCV genotype 1, 2 or 3, to eradicate detectable HCV-RNA by a method comprising administering an effective amount of ribavirin in association with an effective amount of pegylated interferon alpha, characterised in that treating patients having chronic hepatitis C infections is effected in two treatment time periods: (a) a first treatment time period of at least 20 to 30 wherein a therapeutically effective amount of ribavirin and a therapeutically effective induction dosing amount of pegylated interferon-alfa, e.g., pegylated interferon-alfa-2b sufficient to at least substantially lower, and preferably to eradicate, detectable HCV-RNA, are administered; and (b) a second treatment time period of at least 20 to 30 weeks wherein a therapeutically effective amount of ribavirin and a therapeutically effective amount of pegylated interferon-alfa are administered sufficient to maintain no detectable HCV-RNA for at least 20-30 weeks are administered after the end of the first treatment time period and to maintain no detectable HCV-RNA for at least 24 weeks after the end of the second treatment time period is disclosed.		

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INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US 99/27935

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K38/21 A61K31/7056 A61P31/14

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P, X	P. GLUE ET AL.: "A DOSE-RANGING STUDY OF PEG-INTRON AND RIBAVIRIN IN CHRONIC HEPATITIS C. SAFETY, EFFICACY AND VIROLOGIC RATIONALE" HEPATOLOGY (SUPPLEMENT), vol. 30, no. 4(2), October 1999 (1999-10), page 303A XP002138613 USA abstract -/-	1-25

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

25 May 2000

Date of mailing of the international search report

28/06/2000

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/27935

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No. --
P, X	M.SULKOWSKI ET AL.: "COMBINATION THERAPY WITH PEGINTERFERON ALPHA-2A (PEG-IFN) AND RIBAVIRIN IN THE TREATMENT OF PATIENTS WITH CHRONIC HEPATITIS C (CHC)" HEPATOLOGY (SUPPLEMENT), vol. 30, no. 4(2), October 1999 (1999-10), page 197A XP002138614 USA abstract	1-25
P, X	JAYANT TALWALKAR ET AL.: "COMBINATION THERAPY WITH INTERFERON-ALFA-2B (INTRON-A) AND RIBAVIRIN (REBETOL) IN CHRONIC HEPATITIS C PATIENTS PREVIOUSLY RELAPSING OR NOT RESPONDING TO INTERFERON" HEPATOLOGY (SUPPLEMENT), vol. 30, no. 4(2), October 1999 (1999-10), page 197A XP002138615 USA abstract	1-25
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P, X	MITCHELL SCHIFFMAN MITCHELL ET AL.: "CONTROLLED, RANDOMIZED, MULTICENTER, DESCENDING DOSE PHASE II TRIAL OF PEGYLATED INTERFERON ALPHA-2A (PEG) VS STANDARD INTERFERON ALPHA-2A (IFN) FOR TREATMENT OF CHRONIC HEPATITIS C" GASTROENTEROLOGY, vol. 116, no. 4(2), April 1999 (1999-04), page 1275 XP002138617 USA abstract	1-25
P, X	EP 0 956 861 A (SCHERING CORPORATION) 17 November 1999 (1999-11-17) the whole document claims 1-12	1-25
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